IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

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Case: **Polyganics-2(P52147US00)**

Serial No.: Filed:

Group Art Unit:

Examiner:

Title: **BIOMEDICAL POLYURETHANE-AMIDE, ITS PREPARATION AND USE**

Commissioner of Patents
Box **Patent Application**
Washington, D.C. 20231

S I R:

PRELIMINARY AMENDMENT

Please amend the above-identified patent application which is simultaneously filed herewith, as follows:

IN THE CLAIMS-

To facilitate entry of the following changes, the Applicants have also submitted herewith substitute pages providing all the pending claims, as they now stand, incorporating the changes indicated below.

Amend the following claims:

Claim 3,	line 1	Delete "or 2";
Claim 4,	line 1	Change "1-3" to --1--;
Claim 5,	line 1	Change "1-4" to --1--;
Claim 6,	line 1	Change "1-2" to --1--;
Claim 8,	line 1	Change "1-7" to --1--;
Claim 10,	line 1	Delete "or 9";
Claim 11,	line 1	Change "1-10" to --1--;
Claim 14,	lines 1 & 2	Delete "or 13";
Claim 15,	line 1	Change "12-14" to --12--;
Claim 16,	line 2	Change "1-15" to --1--;
Claim 18,	line 1	Delete "or 17";
Claim 19,	line 1	Change "16-18" to --16--;
Claim 20,	line 1	Change "16-19" to --16--;
Claim 21,	line 1	Change "16-20" to --16--;
Claim 22,	line 1	Change "16-21" to --16--;

Amend claims 23-25 as shown.

23. (Amended) Macroporous biomedical polyurethane-amide material according to claim 1[-15, or produced in accordance with the process of claim 16-22,] for use in human or veterinary surgery, as implant or repair material.

24. (Amended) Implant or reconstruction material in human or veterinary surgery based on the biomedical polyurethane-amide [polyurethane-amidess] according to claim 1[-15, or produced in accordance with the process of claim 16-22].

25. (Amended) Porous scaffold for repairing meniscal lesion, comprising the macroporous biomedical polyurethane-amide according to claim 1[-15, or produced in accordance with the process of claim 16-22].

Add new claims 26-28 as follows.

--26. Macroporous biomedical polyurethane-amide material produced in accordance with the process of claim 16 for use in human or veterinary surgery, as implant or repair material.

27. Implant or reconstruction material in human or veterinary surgery based on the biomedical polyurethane-amide produced in accordance with the process of claim 16.

28. Porous scaffold for repairing meniscal lesion, comprising the macroporous biomedical polyurethane-amide produced in accordance with the process of claim 16. --.

REMARKS

The foregoing amendment is made to eliminate multiple dependent claims.

Respectfully submitted,

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Peter L. Michaelson
Name of person making certification

(P2pamd/92/ks)

1. In situ produced macroporous biomedical polyurethane-amide material based on chain extended isocyanate terminated polyester prepolymer units, wherein the said chain extension has been done with at least one dicarboxylic acid or a hydroxy-carboxylic acid.

2. Polyurethane-amide according to claim 1, wherein the material has a pore structure, wherein the amount of pores having a pore size of >450 μm is less than 10% by volume.

3. Polyurethane-amide according to claim 1, wherein the material has an open cell structure.

4. Polyurethane-amide according to claim 1, wherein the said prepolymer is a prepolymer of soft polyester segments, having a glass transition temperature below 40°C, said prepolymer further optionally containing polyether-polyol segments.

5. Polyurethane-amide according to claim 1, wherein the material shows phase separation into hard an soft phases.

6. Polyurethane-amide according to claim 1, wherein the polyester is based on a polyester prepared by ringopening polymerisation, preferably a random copolyester.

7. Polyurethane-amide according to claim 6, wherein the random copolyester is a copolyester of lactide, glycolide, trimethylene carbonate and/or ε-caprolacton.

8. Polyurethane-amide according to claim 1, further comprising an additional diol segment.

9. Polyurethane-amide according to claim 8, wherein the said additional diol segment is a polyether or a polyester segment.

10. Polyurethane-amide according to claim 8, wherein the said diol segment is incorporated in the material during the reaction of the prepolymer with the chain extender.

11. Polyurethane-amide according to claim 1, based on a copolyester of lactide and ε-caprolacton containing 5 to 95, preferably 40-60 % of units of lactide and 5 to 95, preferably 40-60 % of units of ε-caprolacton, based on number.

12. In situ produced macroporous biomedical polyurethane-amide material based on chain extended prepolymer units of biocompatible soft polyester segments and on hard urethane-amide segments, said material having a compression modulus of at least 100 kPa and a pore size distribution less than 10 vol.% of pores having a pore size > 450 μm.

13. Macroporous biomedical polyurethane-amide according to claim 12, showing phase separation between soft and hard segments.

14. Macroporous biomedical polyurethane-amide according to claim 12, having an open cell structure.

15. Macroporous biomedical polyurethane-amide according to claim 12, said material being biodegradable.

16. Process for the preparation of a macroporous biomedical polyurethane-amide according to claim 1, said process being solvent free and comprising preparing an isocyanate terminated polyester prepolymer, mixing the prepolymer with at least one chain extender selected from the group of dicarboxylic acids and hydroxycarboxylic acids, reacting the mixture to produce the macroporous biomedical polyurethane.

17. Process according to claim 16, wherein the said chain extender is adipic acid.

18. Process according to claim 16, wherein the prepolymer is mixed with salt crystals of a required particle size to assist in the generation of suitable pores, and leaching out the salt crystals after the chain extension has been completed.

19. Process according to claim 16, wherein the chain extension is performed in the additional presence of a diol.

20. Process according to claim 16, wherein a nucleant is present during chain extension, said nucleant preferably being either powdered adipic acid, also acting as chain extender, or a powdered inert material.

21. Process according to claim 16, wherein during the chain extension the reaction mixture is treated ultrasonically.

22. Process according to claim 16, wherein the reaction mixture also contains a surfactant.

23. Macroporous biomedical polyurethane-amide material according to claim 1 for use in human or veterinary surgery, as implant or repair material.

24. Implant or reconstruction material in human or veterinary surgery based on the biomedical polyurethane-amide according to claim 1.

25. Porous scaffold for repairing meniscal lesion, comprising the macroporous biomedical polyurethane-amide according to claim 1.

26. Macroporous biomedical polyurethane-amide material produced in accordance with the process of claim 16 for use in human or veterinary surgery, as implant or repair material.

27. Implant or reconstruction material in human or veterinary surgery based on the biomedical polyurethane-amide produced in accordance with the process of claim 16.

28. Porous scaffold for repairing meniscal lesion, comprising the macroporous biomedical polyurethane-amide produced in accordance with the process of claim 16.